

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Confirmation No.: 3624

Ni et al.

Art Unit:

1646

Appl. No.: 10/648,825

Examiner:

Kaufman, Claire M.

Filed: August 27, 2003

Atty. Docket: 1488.131000C/EJH/SAC

Death Domain Containing For: Receptor-5 Antibodies and

Methods of Use (As Amended)

Eleventh Supplemental Information Disclosure Statement Filing under 37 C.F.R. § 1.97(c).

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Eleventh Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Tenth Information Disclosure Statement filed on December 6, 2006 in connection with the above-captioned application.

Copies of AO5, and AR72 to AR82 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent publications, documents **AB5** to AC5 cited on the attached IDS Form PTO/SB/08A, are not submitted.

In addition, the Examiner's attention is directed to the following Interference Nos. 105,361; 105,240; 105,380 and 105,381 which are directed to related subject matter. Applicants have cited patents, patent applications, and non-patent references listed in the

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Exhibit Lists for Interference Nos. 105,361; 105,240; 105,380 and 105,381 that have not already been made of record in the above-captioned application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants' would like to bring to the attention of the Examiner that, for the following document, the publication month could not be determined to the best of the Applicants' ability: **AT72**, Naismith, J.H., *et al.*, "Tumor Necrosis Factor Receptor Superfamily," *J. Inflammation 47*:1-7, Wliey-Liss, Inc. (1996). Applicants believe that the document was published in the beginning of 1996 but could not determine the exact month of publication.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

a. Caull

Shannon A. Carroll, Ph.D. Attorney for Applicants

Registration No. 58,240

Date:

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

Cember 19, 2006

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Complete if Known

10/648,825 August 27, 2003

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S ₂	Substitute form 1449/PTO
V	TABLE ENTH SUPPLEMENTAL
	INFORMATION DISCLOSURE
	STATEMENT BY APPLICANT

(Use as many sheets as necessary)

First Named Inventor Jian Ni Art Unit 1646 **Examiner Name** Kaufman, Claire M. 1488.131000C/EJH/SAC Attorney Docket Number of

Filing Date

Application Number

	-		U.S. PATENT DO	CUMENTS	
Examiner Initials	Cite No. ¹	Document Number Number-Kind Code ^{2 (If Known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages
					or Relevant Figures Appear
	AB5	6,265,556	07/24/2001	Reed et al.	
	AC5	6,642,358	11/04/2003	Rauch et al.	
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[Fo	REIGN PATENT DO	DCUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code' Number Kind Code' (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	AO5	WO 92/01810 A1	02/06/1992	Lerner, Michael and Lerner Ethan		

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Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. • Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. • Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to by the USPTO to process) an application. Confidentially is governed by 35 0.3.C. 122 and 37 CFK 1.14. This collection is estimated to take 2 flours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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DEC: 1 9 2006 Substitute 6 form 1449/PTO Complete if Known 10/648,825 Application Number **単位VENTH SUPPLEMENTAL** Filing Date August 27, 2003 INFORMATION DISCLOSURE First Named Inventor Jian Ni STATEMENT BY APPLICANT Art Unit 1646 (Use as many sheets as necessary) Examiner Name Kaufman, Claire M. 1488.131000C/EJH/SAC Sheet of Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	, , , , , , , , , , , , , , , , , , ,		T ²
·	AR72	Liu, Z.G., et al., "Dissection of TNF Receptor 1 Effector Functions: JNK Activation Is Not Linked to Apoptosis While NF-κB Activation Prevents Cell Death," Cell 87:565-576, Cell Press (November 1996)	
	AS72	Johnson, N.L., et al., "Signal Transduction Pathways Regulated by Mitogenactivated/Extracellular Response Kinase Kinase Kinase Induce Cell Death," J Biol. Chem. 271:3229-3237, The American Society for Biochemistry and Molecular Biology (February 1996)	
	AT72	Naismith, J.H., et al., "Tumor Necrosis Factor Receptor Superfamily," J. Inflammation 47:1-7, Wliey-Liss, Inc. (1996)	
	AR73	Mackey, F., et al., "Lymphotoxin β Receptor Triggering Induces Activation of the Nuclear Factor κβ Transcription Factor in Some Cell Types," J. Biol. Chem. 271:24934-24938, The American Society for Biochemistry and Molecular Biology, Inc. (October 1996)	
	AS73	Rennert, P.D., et al., "Surface Lymphotoxin α/β Complex Is Required for the Development of Peripheral Lymphoid Organs," J. Exp. Med. 184:1999-2006, The Rockefeller University Press (November 1996)	
	AT73	Eischen, C.M., et al., "Comparison of Apoptosis in Wild-Type and Fas-Resistant Cells: Chemotherapy-Induced Apoptosis Is Not Dependent on Fas/Fas Ligand Interactions," Blood 90:935-943, The American Society of Hematology (August 1997)	
	AR74	Chapman, B.S., "A region of the 75 kDa neurotrophin receptor homologous to the death domains of TNFR-1 and Fas," <i>FEBS Lett 374</i> :216-220, Elsevier Science Ltd. (1995)	
	AS74	Beg, A.A. and Baltimore, D., "An Essential Role for NF-κB in Preventing TNF-α-Induced Cell Death," <i>Science 274</i> :782-784, American Association for the Advancement of Science (November 1996)	
	AT74	Van Antwerp, D.J., <i>et al.</i> , "Suppression of TNF-α-Induced Apoptosis by NF-κB," <i>Science</i> 274:787-789, American Association for the Advancement of Science (November 1996)	
	AR75	Wang, CY., et al., TNF- and Cancer Therapy-Induced Apoptosis: Potentiation by Inhibition of NF-κB," Science 274:784-787, American Association for the Advancement of Science (November 1996)	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO	Con	nplete if Known
ELEVENTH SUPPLEMENTAL	Application Number	10/648,825
	Filing Date	August 27, 2003
INFORMATION DISCLOSURE	First Named Inventor	Jian Ni
STATEMENT BY APPLICANT	Art Unit	1646
(Use as many sheets as necessary)	Examiner Name	Kaufman, Claire M.
Sheet 2 of 4	Attorney Docket Number	1488.131000C/EJH/SAC

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	AS75	Hess, S. and Engelmann, H., "A Novel Function of CD40: Induction of Cell Death in Transformed Cells," <i>J. Exp. Med.</i> 183:159-167, The Rockefeller University Press (January 1996)	
	AT75	Sato, T., et al., "A novel member of the TRAF family of putative signal transducing proteins binds to the cytosolic domain of CD40," FEBS Lett. 358:113-118, Elsevier Science Ltd. (1995)	
	AR76	Liu, YJ., et al., "Mechanism of antigen-driven selection in germinal centres," Nature 342:929-931, Nature Publishing Company (1989)	
	AS76	Tsubata, T., et al., "B-cell apoptosis induced by antigen receptor crosslinking is blocked by a T-cell signal through CD40," Nature 364:645-648, Nature Publishing Company (1993)	
	AT76	Hsu, et al., "The TNF Receptor 1-Associated Protein TRADD Signals Cell Death and NF-κB Activation," Cell 81:495-504, Cell Press (1995)	
	AR77	Reed, J.C., "Mechanisms of Apoptosis," Am. J. Pathol. 157:1415-1430, American Society for Investigative Pathology (November 2000)	
	AS77	Doctor, K.S., et al., "The apoptosis database," Cell Death Different. 10:621-633, Nature Publishing Group (June 2003)	
	AT77	Reed, J.C., et al., "The Domains of Apoptosis: A Genomics Perspective," Sci. STKE re9:1-29, American Association for the Advancement of Science (June 2004)	
	AR78	Copy of U.S. Application No. 09/378,045, inventor Rauch, C., filed August 20, 1999 (NOT PUBLISHED)	
	AS78	Dempsey, P.W., et al., "The signaling adaptors and pathways activated by TNF superfamily," Cytokine Growth Rev. 14:193-209, Elsevier Science Ltd. (June-August 2003)	

Examiner	Date
Signature	Considered

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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ELEVENTH SUPPLEMENTAL	Application Number	10/648,825		
	Filing Date	August 27, 2003		
INFORMATION DISCLOSURE	First Named Inventor	Jian Ni		
STATEMENT BY APPLICANT	Art Unit	1646		
(Use as many sheets as necessary)	Examiner Name	Kaufman, Claire M.		
Sheet 3 of 4	Attorney Docket Number	1488.131000С/ЕJH/SAC		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	AT78	Headon, D.J., et al., "Gene defect in ectodermal dysplasia implicates a death domain adapter in development," Nature 414:913-916, Nature Publishing Company (December 2001)	
	AR79	Bridgham, J.T., et al., "All in the family: evolutionary and functional relationships among death receptors," Cell Death Different. 10:19-25, Nature Publishing Company (January 2003)	
	AS79	Pawlowski, K., et al., "From fold to function predictions,: an apoptosis regulator protein BID," Comp. Chem. 24:511-517, Elsevier Science Ltd. (May 2000)	
	AT79	Jang, YJ., et al., "Analysis of the phenotypes of Jurkat clones with different TRAIL-sensitivities," Cancer Lett. 194:107-117, Elsevier Science Ltd. (May 2003)	
	AR80	Daniels, R.A., et al., "Expression of TRAIL and TRAIL receptors in normal and malignant tissues," Cell Res. 15:430-438, Institute of Biochemistry and Cell Biology (June 2005)	
	AS80	Gong, B. and Almasan, A., "Apo2 Ligand/TNF-related Apoptosis-inducing Ligand and Death Receptor 5 Mediate the Apoptotic Signaling Induced by Ionizing Radiation in Leukemic Cells," Canc. Res. 60:5754-5760, American Association for cancer Research (October 2000)	
	AT80	Yun, T.J., et al., "OPG/FDCR-1, a TNF Receptor Family Member, Is Expressed in Lymphoid Cells and Is Up-regulated by Ligating CD40," J. Immunol. 161:6113-6121, American Association of Immunologists (December 1998)	
	AR81	Screaton, G.R., et al., "TRICK2, a new alternatively spliced receptor that transduces the cytotoxic signal from TRAIL," Curr. Biol. 7:693-696, Current Biology Ltd. (September 1997)	
	AS81	Clancy, L., et al., "Preligand assembly domain-mediated ligand-independent association between TRAIL receptor 4 (TR4) and TR2 regulates TRAIL-induced apoptosis," Proc. Natl. Acad. Sci. USA 102:18099-18104, National Academy of Sciences (December 2005)	

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Signature	Considered

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Substitute for form 1449/PTO				Complete if Known		
ELEVENTH SUPPLEMENTAL				Application Number	10/648,825	
INFORMATION DISCLOSURE				Filing Date	August 27, 2003	
				First Named Inventor	Jian Ni	
STATEMENT BY APPLICANT (Use as many sheets as necessary)				Art Unit	1646	
				Examiner Name	Kaufman, Claire M.	
Sheet	4	of	4	Attorney Docket Number	1488.131000C/EJH/SAC	

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²			
	AT81	Mongkolsapaya, J., et al., "Cutting Edge: Lymphocyte Inhibitor of TRAIL (TNF-Related Apoptosis-Inducing Ligand): A New Receptor Protecting Lymphocytes from the Death Ligand TRAIL," J. Immunol. 160:3-6, The American Association of Immunologists (January 1998)				
	AR82	Mongkolsapaya, J., et al., "Structure of the TRAIL-DR5 complex reveals mechanisms conferring specificity in apoptotic initiation," Nat. Struct. Biol. 6:1048-1053, Nature America Inc. (November 1999)				
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December 19, 2006

Christopher J. Walsh W. Blake Coblentz* James J. Pohl* John T. Haran Mark W. Rygiel Kevin W. McCabe Michael R. Malek* Doyle A. Siever*

Ulrike Winkler*

Registered Patent Agents -Karen R. Markowicz Matthew J. Dowd Katrina Yujian Pei Quach Bryan L. Skelton Robert A. Schwartzman Julie A. Heider Mita Mukherjee Scott M. Woodhouse Peter A. Socarras Jeffrey K. Mills Danielle L. Letting Lori Brandes Steven C. Oppenheimer

<u>Of Counsel</u> Edward J. Kessler Kenneth C. Bass II Marvin C. Guthrie

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WRITER'S DIRECT NUMBER: (202) 772-8822 INTERNET ADDRESS: SCARROLL@SKGF.COM

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Art Unit 1646 Mail Stop Amendment

Re:

U.S. Utility Patent Application

Application No. 10/648,825; Filed: August 27, 2003

For: Death Domain Containing Receptor-5 Antibodies and Methods of Use

(As Amended)

Inventors: Ni et al.

Our Ref: 1488.131000C/EJH/SAC

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover the IDS fee;
- 2. Eleventh Supplemental Information Disclosure Statement Filing under 37 C.F.R. §1.97(c);
- 3. Form PTO/SB/08A (1 page) listing three (3) cited documents (AB5, AC5 and AO5);
- 4. Form PTO/SB/08B (4 pages) listing 31 cited documents (AR72-AR82);
- 5. Copies of 32 cited documents (AO5 and AR72-AR82); and
- 6. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox PLLC.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

Commissioner for Patents December 19, 2006 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Shannon A. Carroll, Ph.D.
Attorney for Applicants

Registration No. 58,240

EJH/SAC:kim Enclosures 622165_1.DOC

Sterne, Kessler, Goldstein & Fox PLLC. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f 202.371.2540 : www.skgf.com